REMARKS

This responds to the Office Action mailed on March 5, 2004.

Claims 2, 4, 13, 15-18, 29 and 30 are amended. No claims are canceled or added. As a result, claims 2 – 35 remain pending in this patent application.

§102 Rejection of the Claims

Claims 2-8, 15-25 and 28-35 were rejected under 35 U.S.C. § 102(b) for anticipation by Hudrlik (U.S. Patent No. 5,282,840). Applicant respectfully traverses.

Applicant cannot find in the cited portions of Hudrlik any disclosure of using a baseline portion of the detected thoracic impedance below about 0.5 Hz, as presently recited or incorporated in these claims. The present patent specification also creates the following clear and express definition of baseline as that portion of the thoracic impedance signal that is influenced by intravascular fluid shifts to and away from the thorax:

> A "dc" or "baseline" or "low frequency" component of the thoracic impedance signal (e.g., less than a cutoff value that is approximately between 0.1 Hz and 0.5 Hz, inclusive, such as, for example, a cutoff value of approximately 0.1 Hz) provides information about the subject patient's thoracic fluid tension, and is therefore influenced by intravascular fluid shifts to and away from the thorax. Higher frequency components of the thoracic impedance signal are influenced by the patient's breathing (e.g., approximately between 0.05 Hz and 2.0 Hz inclusive) and heartbeat (e.g., approximately between 0.5 Hz and 10 Hz inclusive).

(Application at page 9, lines 6 – 14.) By contrast Hudrlik uses a "wide band impedance." (*See* Hudrlik at column 2, lines 24 – 25.) The wide band impedance of Hudrlik includes using two frequencies, F1 and F2, that each exceed 10 Hz, and which therefore fall outside the express definition of baseline set forth in the present patent application. (*See id.* at FIG. 3.)

Similarly, Applicant can find no disclosure in the cited portions of Hudrlik of using a baseline portion of the detected thoracic impedance that indicates a fluid shift away from the thorax, as recited or incorporated these claims of the present patent application. The Office Action erroneously asserts that "Hudrlik . . . detects a fluid shift away from the thorax (creating ischemia of the tissue)." (Office Action ¶ 3.) Applicant strongly disagrees with this alleged linkage between any fluid shift from the thorax and the "ischemia" referred to in Hudrlik.

Applicant cannot find any mention anywhere in Hudrlik of detecting a fluid shift away

from the thorax. Moreover, the ischemia referred to in Hudrlik is *cardiac* ischemia, and not any alleged thoracic ischemia caused by fluid shift away from the thorax, as was apparently misinterpreted in the Office Action. As Hudrlik clearly states:

> multiple frequency excitation signals may be used to detect *cardiac* tissue distress, such as ischemia or the response of the tissue to drug treatment.

(Hudrlik at column 3, lines 9 – 11 (emphasis added).) In sum, neither the cardiac ischemia or anything else discussed in Hudrlik discloses, teaches, or even suggests using a baseline thoracic impedance below about 0.5 Hz that relates in any way to a fluid shift away from the thorax. Because Hudrlik does not disclose all elements recited or incorporated in claims 2-8, 15-25 and 28-35, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

§103 Rejection of the Claims

1. Claims 9-12, 26 and 27 were rejected under 35 U.S.C. § 103(a) for obviousness over Hudrlik (U.S. Patent No. 5,282,840) in view of Combs et al. (U.S. Patent No. 5,957,861). Applicant respectfully traverses.

The Office Action states that "Hudrlik discloses the claimed invention except for the cutoff frequency for the fluid impedance signal being 0.01 to 0.5 Hz, or approximately 0.1 Hz." Applicant respectfully traverses any assertion that Hudrlik discloses the claimed subject matter, except for this cutoff frequency For example, as discussed above with respect to the §102 rejection, there is no evidence of record that links cardiac ischemia referred to in Hudrlik to a fluid shift away from the thorax.

Moreover, Applicant respectfully submits that the combination of Combs et al. and Hudrlik fails for several reasons. First, Hudrlik is not silent on the thoracic impedance frequencies that it uses, such that Combs et al. could somehow be combined with Hudrlik without any conflict. Instead, FIG. 3 of Hudrlik specifically discloses using two impedance frequencies, F1 and F2, each of which exceed 10 Hz. This expressly and specifically conflicts with and contradicts the alleged teaching of Combs et al. of using a lowpass cutoff frequency of 0.1 to 0.5 Hz. In other words, combining Combs et al. with Hudrlik would render Hudrlik inoperable for its intended purpose, that is:

> Two or more excitation frequencies are typically used, one at an impedance peak, one displaced from the impedance peak, preferably at a frequency which defines an impedance minimum. The excitation frequencies should be chosen such that the event of interest causes a substantial change in the relative values in the impedances at the excitation frequencies.

(Hudrlik at column 3, lines 1 – 8.) Therefore, using the lowpass cutoff frequency of Combs et al. would remove the very impedance signal frequencies measured by Hudrlik. This makes it wholly inappropriate to combine Combs et al. with Hudrlik.

Second, each of Combs et al. and Hudrlik actually teaches away from using a baseline thoracic impedance to detect a fluid shift away from the thorax. As set forth in Applicant's previous responses during examination of this patent application, Combs et al. relates to edema, a fluid accumulation in the thorax—this is directly opposite to the presently claimed fluid shift away from the thorax. The Examiner has already recognized these previous arguments by the Applicant as convincing. (See Office Action ¶ 2.) Moreover, Hudrlik teaches away from using a baseline component of the thoracic impedance (below 0.01 to 0.5 Hz, or approximately 0.1 Hz) by expressly teaching the use of two frequencies, F1 and F2, that exceed 10 Hz. (*See* Hudrlik at FIG. 3.)

Third, Applicant cannot find in either Combs et al. or Hudrlik any motivation for combining these two references. The Office Action states:

> It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an impedance measurement frequency range of 0.01 to 0.5 Hz, or approximately 0.1 Hz in the Hudrlik system in order to avoid extraneous noise in the fluid impedance signal so an accurate determination of the fluid level can be determined (col. 6 @ 58 – col. 7 @ 33).

(Office Action ¶ 5.) Applicant has searched the above-cited portion of the Hudrlik reference, but cannot find the stated motivation for combining these two references. To the extent that such a motivation is relying on information within the Examiner's personal knowledge, the Applicant timely objects to such reliance on Official Notice, and respectfully requests that the Examiner provide a reference as evidence to support such an assertion, as required by MPEP § 2144.03.

For the reasons set forth above, Applicant respectfully requests withdrawal of this basis of this rejection of these claims.

2. Claims 13 and 14 were rejected under 35 U.S.C. § 103(a) for obviousness over Sheldon et al. (U.S. Patent No. 6,044,297) in view of Pitts Crick et al. (U.S. Patent No. 6,104,949) and further in view of Hudrlik (U.S. Patent No. 5,282,840). Applicant respectfully traverses.

First, the rejection admits that "Sheldon et al. disclose the claimed invention except for using transthoracic impedance to indicate hypotension." (Office Action ¶ 6.) However, to the extent that the rejection is attempting to use Pitts Crick et al. to provide this missing element, Applicant respectfully disagrees. As noted in Applicant's previous Response mailed on January 16, 2004, Pitts Crick et al. actually teaches away from detecting thoracic hypotension (a fluid shift *away* from the thorax) because it is directed toward detecting edema (a fluid shift *toward* the thorax). The Examiner has already recognized these previous arguments by the Applicant as convincing. (See Office Action ¶ 2.)

Although Pitts Crick et al. acknowledges posture-related fluid shifts affecting transthoracic impedance, it apparently treats such information not as a desirable signal of interest, but rather, as *noise* confounding its edema assessment. More particularly, Pitts Crick et al. states:

> These impedance measurements should represent the impedance changes caused by fluid changes in the trans-thoracic tissues, especially in the lungs, due to the patient's posture changing. Therefore, it is important to either filter or collect several samples and calculate the average, to remove [it] and cardiac or respiratory component from the signal.

(Pitts Crick et al. at column 5, lines 36 - 42.) Because Pitts Crick et al. apparently operates to correlate to—and then remove—the effect of the patient's postural changes, Applicant respectfully submits that it actually teaches away from these claims.

Moreover, Pitts Crick et al. also teaches away from providing a therapy that assists in shifting fluid back toward the thorax, as presently recited or incorporated in these claims. More particularly, Pitts Crick et al. discusses how its therapy operates by stating:

> If such treatments are successful, then the values sensed by the device should move in a direction opposite to that Shown in FIGS. 4A, 4B, and 4C. That is if a patient with severe HF, with an impedance response as shown in FIG. 4C, receive adequate treatment, the resulting curve might convert to FIG. 4B and patient with moderate HF as in FIG. 4B might convert to FIG. 4A.

(Pitts Crick et al. at column 6, lines 43 – 49.) As seen in these figures of the Pitts Crick et al. reference, the therapy used by Pitts Crick et al. actually increases thoracic impedance, which, as explained above, corresponds to shifting fluid away from the thorax. By contrast, Applicants claims presently recite or incorporate providing a therapy to shift fluid back toward the thorax. Therefore, Pitts Crick et al. actually teaches away from the present claims and from any alleged hypotension detection of Sheldon et al. Therefore, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Second, Applicant takes this opportunity to respond to certain remarks made in the rejection in support of combining Pitts Crick et al. and Sheldon et al. The Office Action states:

> The Applicant states treatment of hypotension can be based on trans-thoracic impedance and one or more secondary variables such as an [accelerometer] to detect posture changes (specification – page 10, lines 15 – 19), hence absent any teaching of criticality or unexpected results, merely changing the basis of treatment of hypotension from an impedance sensor to impedance and activity sensors would have been an obvious design choice.

(Office Action ¶ 6.) Applicant respectfully objects to these remarks on two grounds. First, there is nothing in claims 13 – 14 (in relation to which these remarks were made) that specifically recites using an activity sensor. Therefore, Applicant respectfully believes that these remarks are inappropriate with respect to claims 13 and 14, and Applicant respectfully requests that these remarks be withdrawn from the record. Second, without admitting to or asserting any "criticality" or "unexpected results," Applicant submits that the quoted remarks from the specification must be understood in the context in which they were made. Indeed, the specification of the present patent application states:

> By using thoracic impedance to directly measure thoracic intravascular fluid tension, rather than measuring a change of posture or other secondary variable, system 100 provides more reliable treatment of thoracic hypotension and its associated symptoms. However, it is understood that in one embodiment, system 100 bases its treatment of hypotension based not only on the thoracic impedance-based measurement of intravascular fluid tension, but also [on] one or more of these secondary variables (e.g., also using an accelerometer to detect a change in posture).

(Application at page 10, lines 12 – 19.) Therefore, the present patent application expressly explains that transthoracic impedance provides a more direct assessment of hypotension than other techniques, although such other auxiliary techniques that involve measuring a secondary

variable could be used to augment this more direct transthoracic impedance based indication of hypotension. Using an accelerometer to indicate postural hypotension may fail to detect non-postural hypotension. Similarly, using a detected drop in heart rate to infer thoracic hypotension may not accurately predict whether any thoracic hypotension actually occurs as a result of a drop in this secondary variable of heart rate, and would not be able to accurately quantify an actual level of hypotension resulting from the drop in heart rate. By contrast, the present transthoracic impedance measurement provides a direct indication of whether there is a fluid shift away from the thorax, the amount of such fluid shift away from the thorax, and how much fluid is returned to the thorax by any responsive therapy that is delivered. Applicant can find no disclosure, teaching, or suggestion of such direct measurement of thoracic hypotension in any of the cited references.

Third, the rejection admits that "Sheldon et al. disclose the claimed invention except the therapy shifting the fluid back to the thorax." (Office Action ¶ 6.) However, to the extent that the rejection is attempting to use Hudrlik et al. to provide this missing element, Applicant respectfully disagrees. For the reasons discussed above, Hudrlik applies merely to *cardiac* ischemia, rather than to thoracic ischemia or thoracic hypotension. Claim 13 has been amended to clarify that the detected hypotension is a thoracic hypotension rather than the cardiac ischemia referred to in Hudrlik. Accordingly, this claim is believed allowable, because there is no evidence of any motivation to combine Hudrlik and Sheldon et al. and, as discussed above, Hudrlik uses a portion of the thoracic impedance frequency spectrum that is unrelated to any fluid shift away from the thorax. Therefore, Applicant respectfully submits that no *prima facie* case of obviousness presently exists with respect to these claims.

For the reasons discussed above, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

3. Claims 13 and 14 were rejected under 35 U.S.C. § 103(a) for obviousness over Sheldon et al. (U.S. Patent No. 6,044,297) in view of Ferek-Petric et al. (U.S. Patent No. 5,913,897) and further in view of Standberg (EP 0620420A1) and further in view of Hudrlik (U.S. Patent No. 5,282,840). Applicant respectfully traverses.

The rejection states that "Sheldon et al. disclose the claimed invention except for using transthoracic impedance to indicate hypotension." Without admitting that the remainder of the

claimed invention is disclosed by Sheldon et al., Applicant agrees with the Examiner's conclusion that Sheldon et al. does not disclose using transthoracic impedance to indicate hypotension. Moreover, Applicant has amended claim 13 to clarify that the invention recited in claim 13 uses transthoracic impedance to indicate how much fluid is present in a thorax. Applicant cannot find any disclosure, teaching, or suggestion of this in the cited portions of any of the references (i.e., Ferek-Petric et al., Standberg, or Hudrlik.

For example, Ferek-Petric et al. apparently uses an impedance (not necessarily a transthoracic impedance) to measure blood flow (*see* Ferek-Petric et al. at column 2, lines 51 – 55), not how much fluid is present in a thorax. It does so by using a sensor implanted within the right heart (*see id.* at column 3, lines 16 -18) to measure venous pooling, which is presumably indicated by a reduced venous return flow (*see id.* at column 3, lines 33 – 34). However, Applicant can find nothing in the cited portions of Ferek-Petric et al. that would be capable of distinguishing between venous pooling in the thorax (e.g., associated with pulmonary edema) or venous pooling in the lower extremities or otherwise representing a fluid shift away from the thorax. By contrast, the present claims recite using a transthoracic impedance to provide a more direct indication of how much fluid is present in a thorax, such that any hypotension resulting from a fluid shift away from the thorax can be more accurately detected and treated.

Likewise, as discussed above, Applicant respectfully submits that Hudrlik fails to disclose, teach, or suggest using an implantable medical device to indicate thoracic hypotension resulting from a fluid shift away from the thorax using transthoracic impedance to indicate how much fluid is present in a thorax, as presently recited or incorporated in claims 13 – 14. In making this rejection, the Office Action states:

> Hudrlik discloses an implantable stimulation device to manage fluid flow and teaches that gross tissue insults, created by a significant reduction of blood flow to tissue of the thorax, cause dramatic shifts in the impedance (col. 2 @ 32 – 35).

(Office Action ¶ 7.) Applicant disagrees with any assertion that Hudrlik pertains to a reduction in blood flow to the thorax. When read in context, it is clear that Hudrlik pertains merely to *cardiac* ischemia (*see* Hudrlik at column 3, lines 9 – 11), and completely fails to address thoracic hypotension. As explained above, Hudrlik apparently uses a portion of the thoracic impedance frequency spectrum (above 10 Hz) that Applicant believes has no relation to any fluid shift from the thorax, as recited in the present claims. Therefore, there is no evidence indicating the

Hudrlik would be effective at detecting thoracic hypotension as indicated by a thoracic fluid level that is impacted by a hypotensive fluid shift away from the thorax. Accordingly, Applicant respectfully submits that it is improper to combine Hudrlik with Sheldon et al. or the other references.

For the reasons discussed above, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

AVRAM SCHEINER ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6951

Date June 7, 2004

By _____
Suneel Arora
Reg. No. 42,267

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, MS: Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, on this 7 day of June, 2004.

Paula Suchy
Name

Paula Suchy
Signature